Clinical Summary:

Association of patient factors and bioprosthesis size with hemodynamic change over 5 years following RESILIA tissue-based aortic valve replacement

Mumtaz MA, Bavaria JE, Griffith B, et al. Presented at the Society of Thoracic Surgeons Annual Meeting, January 2022.

Inspiring Results

Objective

The COMMENCE aortic trial is an FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with the novel RESILIA tissue. A sub-analysis of the 5-year outcomes of the COMMENCE aortic trial was conducted to evaluate patient and valve factors that impact hemodynamic performance.

Key Points

- In this sub-analysis, the authors sought to associate comorbidities and valve factors related to increased gradients
- In this cohort of patients (mean age 67 years), the average increase in mean gradient over 5 years was mild, and the decrease in effective orifice area (EOA) over 5 years was minimal

Methods

- Patients underwent echocardiograms annually through 5 years of follow up; these were evaluated by a core laboratory.
- Only patients with evaluable echo data (N=663) at any of the post-op visits were eligible for inclusion in this sub-analysis
- Longitudinal models were constructed to estimate the change in mean gradient and change in effective orifice area (EOA) separately over 5 years post-operatively
- Key patient demographics of this sub-analysis cohort at baseline:
  - Mean age was 66.7 ± 11.6 years
  - 71.6% were male
  - Average STS score was 1.9 ± 1.7%
  - Average EuroScore II was 2.5 ± 2.8%
  - Most patients were NYHA Class II (51%)
    - Class I (23%), Class III (24%), Class IV (2%)

Results

- Among various variables examined, only patient age at implant and valve size were statistically significantly associated with mean gradient change over 5 years (Table 1).
- Only valve size was found to be independently associated with a decrease in EOA.
- In the multivariable model, mean gradient over 5 years rose 3.6 mmHg for the typical 55-yr old patient, 2.4 mmHg for the typical 65-yr old patient, and 1.6 mmHg for the typical 75-yr old patient (Figure 1).
- Average 5-year change in EOA was between -0.27 cm^2 and -0.29 cm^2 for these ages.
- In the multivariable model, mean gradient over 5 years rose between 0.9 mmHg and 2.7 mmHg for valve sizes between 21 mm and 27 mm, respectively (Table 2).
- Average 5-year change in EOA was between -0.19 cm^2 and -0.30 cm^2 for these valve sizes.

Table 2. Change in mean gradient over time by valve size

Valve size (mm)	5-year change (mmHg)
19	5.1
21	2.7
23	1.8
25	0.9
27	0.9
29	2.4

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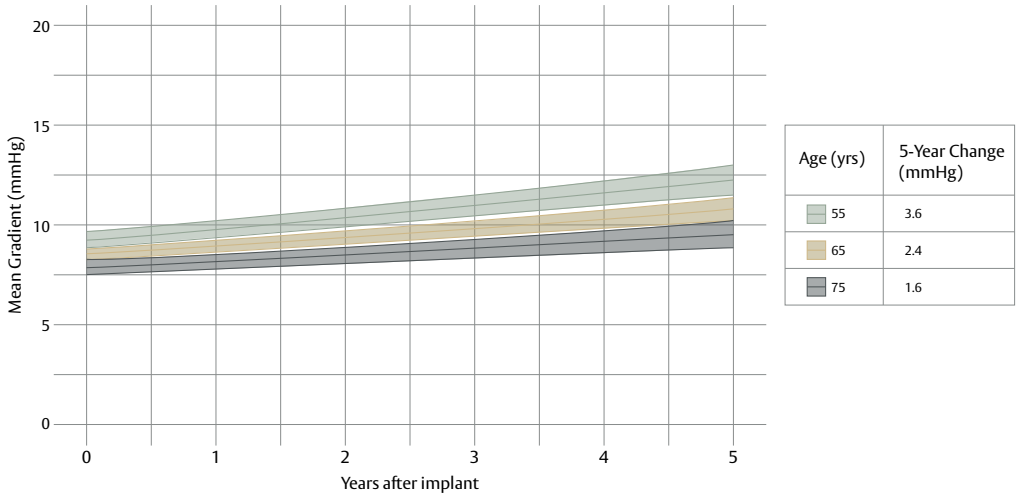
Table 1. Association of patient characteristics and valve size on mean gradient change and EOA change

Factor	% (N=663)	Mean gradient *p* value	EOA *p* value
Renal failure	8.4	0.73	0.39
Diabetes	28.1	0.07	0.07
Hx smoking	48.9	0.55	0.84
Hyperlipidemia	63.0	0.15	0.43
Hypertension	70.1	0.51	0.41
Obesity	44.8	0.14	0.92
eGRF	mean 75.7 ± 19.5 mL/min	0.41	0.84
Age	mean 66.7 ± 11.6 yr	<0.001	0.53
Valve size	19 mm: 3.3%, 21 mm: 19.3% 23 mm: 31.1%, 25 mm: 29.0% 27 mm: 14.5%, 29 mm: 2.9%	0.02	0.02

Figure 1. Change in mean gradient over time by age

Mean gradient over time for 3 selected ages



Conclusions

- Only patient age and valve size were found to be independently associated with an increase in mean gradient over 5 years
- The increase in mean gradient and the decrease in EOA across all ages and valve sizes were minimal.
- These results are encouraging for the potential durability of RESILIA tissue*

**No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.*

Important Safety Information: INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves. **Contraindications:** There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve. **Complications and Side Effects:** Thromboembolism, valve thrombosis , hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-Valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

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